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09/844,061	04/26/2001	Nancy Elisabeth Krauss	R0070B-REG	9572

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EXAMINER

LIU, HONG

ART UNIT	PAPER NUMBER
1624	3

DATE MAILED: 12/14/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/844,061	Applicant(s) Krauss et al.
Examiner Hong Liu	Art Unit 1624

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 835 C.D. 11; 453 O.G. 213.
- 4) Claim(s) 1-49 is/are pending in the application
- 4a) Of the above, claim(s) 20-37 and 44-49 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19 and 38-43 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 20) Other: _____

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DETAILED ACTION

Claims 1-49 are pending in this application.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-19 and 38-43, drawn to the compounds of formula I wherein X and Y are CH, R2 is alkyl, alkenyl, haloalkyl, cycloalkyl, aryl, aralkyl, hydroxyalkyl, alkoxyalkyl, and their pharmaceutical compositions, classified in class 564, subclass 374.
 - II. Claims 1-19 and 38-43, drawn to the compounds of formula I wherein X and Y are CH, R2 is NR13R14, and their pharmaceutical compositions, classified in class 564, subclass 86.
 - III. Claims 1-19 and 38-43, drawn to the compounds of formula I wherein X and Y are CH, R2 is alkoxycarbonylalkyl, and their pharmaceutical compositions, classified in class 560, subclass 12.
 - IV. Claims 1-43, drawn to the compounds of formula I wherein one of X and Y is N and their pharmaceutical compositions, classified in class 546, and respective subclasses.

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V. Claims 1-43, drawn to the compounds of formula I wherein both X and Y are N, and their pharmaceutical compositions, classified in class 544, and respective subclasses.

VI. Claims 44-49, drawn to a method of using the compounds of formula I, classified in class 514, subclass 646.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I-V are directed to structurally dissimilar compounds such that the variable core created by varying the definitions of the formula do not belong to a recognized class of chemical compounds in the art, and references anticipating one invention would not render obvious the others, for example, benzene is different from pyridine. Thus, separate searches in the literature as well as in the U.S. Patent Clarification System would be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structures as functional equivalents of each other. The mere fact that there is a single similarity is not in itself a significant reason to render the whole embodiment obvious.

Inventions I-V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case more than one use exists for compounds of Group I as

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evidenced by claims 44-49 drawn to a variety of diverse uses. Additionally, the various uses would raise issues of enablement separate from that of the compound claims and would require art-recognized evidence that activity relied on its reasonably correlated to in vivo efficacy for the uses claimed..

During a telephone conversation with Mr. Rohan Peries on 12/12/01 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-43. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-37 and 44-49 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-19 and 38-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of “prodrug” is not adequately enabled. Applicants provide no guidance as how the compounds are made more active *in vivo*. The choice of a “prodrug” will vary from drug to drug. Therefore, more than minimal routine experimentation would be required to determine which prodrug will be suitable for the instant invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

5. 1). Claim 1 is vague and indefinite in that it recites the compounds “and prodrugs, individual isomers...” It is not clear whether the claim is drawn to an instantly claimed compound or a mixture . The word “or” is suggested in place of “and.”
6. 2). The use of “heteroaryl” and “heterocycl” in the definition of B and R1 is unclear to the array of heteroatoms, size of the rings, as well as nature of atoms as ring members. See In re Wiggins 179 USPQ 421 for certain terminology regarding heterocyclic ring systems.

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3). The scope of "alkyl", "arylalkyl", "alkoxyalkyl", etc. as recited in claim 1 for the definition of various R reads on carbons of non-limiting length. Long chains would be difficult to prepare and may be too insoluble for instant use. See In re Hawkins 179 USPQ 157 regarding carbon radicals that have unlimited chain lengths and ring sizes in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Sebti et al., Chem Abstract 130:25338. The instantly claimed compounds read on the reference compound, see the enclosed copy of CAPLUS computer search report and the compound having RN 216232-65-4, i.e., R2 is methyl, R1 is phenylmethyl, A is methylene, and B is substituted phenyl. *overcome*

Claims 1, 2, 12, 13, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al. (J. Med. Chem., 1995). Jones teaches the compounds and composition of the instant invention (see Compound 35, p. 907).

Claims 1, 2, 12, 13, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Berman et al. (US Patent 4,857,530). Berman teaches the compounds and composition of the instant invention (see Examples). *overcome*

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Claims 1, 2, 12-14, 16, 17, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirsch et al., Chem Abstract 110: 101836. The instantly claimed compounds read on the reference compound, see the enclosed copy of CAPLUS computer search report and the compound having RN 89985-16-0. *retrun*

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Mattor et al., Chem Abstract 86: 197939. The instantly claimed compounds read on the reference compound, see the enclosed copy of CAPLUS computer search report and the compounds. *return*

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al., Chem Abstract 127:242825. The instantly claimed compounds read on the reference compound, see the enclosed copy of CAPLUS computer search report and the compound having RN 157911-86-9. *does not overcom*

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Barton et al. (J. Am. Chem. Soc., 1993). Barton teaches the compounds and composition of the instant invention (see attached CAS report). *does not overcom*

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 2, 12, 13, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman et al. (US Patent 4,857,530). The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula I, Col. 2 wherein Ar is phenyl substituted with R6 wherein R6 is SO₂R₃ where in is alkyl, R₂ is an alkyl group, etc. The claims differ from the reference by reciting a specific species and/or a more limited genus than the reference. However, it would have nevertheless been obvious to one skilled in the art at the time of the invention to be motivated to select any of the species of the genus taught by the reference including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the specie of the genus would have similar properties and, thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render *prima facie* obvious a species falling within a genus. See *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. V. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

gvl/mhl

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax

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phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for **official** business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

hl
December 13, 2001



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